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**Comments to the FDA
Regulation of Over-the-Counter Drug Products Public Hearing
Docket # 00N-1256**

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2:10 pm
June 29, 2000

Good afternoon. I am Randy Juhl, the Dean of the School of Pharmacy at the University of Pittsburgh. I also serve as the Associate Vice Chancellor for Research Conduct and Compliance. I am here today courtesy of the Consumer Healthcare Products Association who paid for my airfare. In the interest of full disclosure, I serve as a consultant to a variety of consumer products manufacturers about their OTC drug products. On the other side of the fence, I served as the Chair of the Nonprescription Drugs Advisory Committee from its inception in 1992 until the completion of my term in 1996. I am currently the chair of the FDA's Advisory Committee on Pharmacy Compounding.

I would like to address three topics in my brief time before you today: First, the role of the FDA in self-care; second, the tasks of the advisory committee(s); and third, issues that have arisen during the past two days related to the specific questions posed by the agency in the Federal Register notice of this meeting.

1. The Role of the FDA in Self-Care

It is evident to all that self-care is a major trend that will only increase in the coming years. There are several factors catalyzing the popularity of self-care, wellness, fitness or whatever euphemism you choose. I will discuss two of these factors.

First, because of a change in our societal values and an enhanced access to information, consumers desire, or demand, to take a more active role in their own health and wellness. This can be observed by simply viewing the marketplace: health spas, rowing machines, vitamin-fortified foods, sports medicine, fitness centers, heart-healthy diets, exercise videos, nutrition gurus, Diet Coke, reduced-fat food, direct-to-consumer advertising, meditation, dietary supplement purveyors of all types, the Thigh-Master, functional foods, therapeutic magnets, skim milk, treadmills, Lean Cuisine, running shoes, relaxation therapy, fat

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pharmacologists, Simon and Garfunkel, "We'd like to help you learn to help yourself." (From Mrs. Robinson, lyrics by Paul Simon).

I encourage you to continue to actively consider self-care solutions for consumers in new categories. Individual companies are more than capable of assembling an Rx-to-OTC development program for specific drug products. However, there is not a good methodology for establishing new OTC categories. In the distant past, the agency held advisory committee hearings on new categories prior to consideration of an NDA – asthma drugs, nicotine replacement products, recurrent genital herpes, data requirements for analgesic products, to name a few past topics. This approach has not been used in the past few years and might be a better mechanism to openly discuss the barriers to providing consumers additional self-care options.

2. The Advisory Committee

I alluded to the advisory committee and would like to address some comments to the members. I thoroughly enjoyed my time on the Nonprescription Drugs Advisory Committee. However, it also frequently caused me great intestinal distress. Everyone on the committee then, as now, struggled conscientiously with the questions we were asked to consider. The issues were not easy. "If they were easy, we wouldn't need you," said the Office Director on several occasions.

My experiences in this regard were not different from what you currently experience. However, most of you have never had the experience of seeing a drug product that you reviewed actually appear on the pharmacy shelves. During the years 1995 to 1997 there was a flourish of Rx-to-OTC switches. I have included a list of the switch products in your handout. There were several new categories established in that time period. And for each of those new categories, in fact all through the history of switch, predictions of doom were not in short supply. Renal failure and GI bleeds would be rampant from NSAIDs; OTC H₂ receptor antagonists would lead to masked GI cancers – not to mention all the drug interactions: consumers would be using Rogaine in all kinds of inappropriate ways which would delay treatment of various scalp cancers; dogs would die and kids would become hooked on OTC nicotine replacement products; and other potential horror stories.

I am not suggesting that these "the sky is falling" prophesies were trivial – they served very useful purposes in the discussions. But in the end, the data, and common sense, didn't support the predicted worst-case scenarios.

I should also note for the purpose of balance, our committee also recommended that several products not become OTC. The committee was very active, meeting four to five times a year, 2-3 days per meeting, during the early years.

Rx => OTC SWITCH

- 1984 Advil/Nuprin (ibuprofen)
- 1985 Afrin (oxymetazoline)
- 1986 Antiminth (pyrantel pamoate)
- 1987 Drixoral (dextbrompheniramine)
- 1988 Imodium AD (loperamide)
- 1990 Gyne-Lotrimin (clotrimazole)
- 1990 Nix (permethrin)
- 1992 Tavist (clemastine fumarate)
- 1994 Aleve (naproxen sodium)

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1995 Rx => OTC SWITCH

- Pepcid AC (famotidine)
- Tagamet HB (cimetidine)
- Zantac 75 (ranitidine)
- Children's Motrin Susp. (ibuprofen)
- Orudis KT (ketoprofen - Whitehall)
- Actron (ketoprofen - Bayer)
- Femstat3 (butoconazole nitrate 2%)

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1996 Rx => OTC SWITCH

- Ocuhist (pheniramine/naphazoline)
- Nicorette (nicotine gum)
- Rogaine (minoxidil 2%)
- Axid AR (nizatidine)
- Nicotrol/Nicoderm (nicotine patches)
- Children's Advil (ibuprofen)
- Monistat 3 (miconazole 2%)

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1997 Rx => OTC SWITCH

- Nasalcrom (cromolyn sodium)
- Total toothpaste (triclosan + fluoride)
- Nizoral AD shampoo (ketoconazole 1%)
- Vagistat -1 (tioconazole 6.5%)
- Rogaine Extra Strength (minoxidil 5%)
- Imodium Advanced (loperamide + simethicone)

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